



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to glucose and contribution to energy-yielding metabolism pursuant to Article 13(5) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to glucose and contribution to energy-yielding metabolism pursuant to Article 13(5) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Dextro Energy GmbH & Co. KG submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Germany, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to glucose and “it is metabolised within body’s normal energy metabolism”. The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The food constituent that is the subject of the health claim is glucose, which is sufficiently characterised. The claimed effect is “it is metabolised within body’s normal energy metabolism”. The proposed target population is the general population. The Panel notes that the claimed effect refers to the contribution of the food constituent to energy-yielding metabolism, which is a beneficial physiological effect. Glucose is used within cells as a source of energy and contributes to energy-yielding metabolism, which is a property inherent to the food constituent. The publications provided by the applicant as being pertinent to the claim do not add new information to the well established role of glucose in energy-yielding metabolism as a source of energy. The Panel concludes that a cause and effect relationship has been established between the intake of glucose and contribution to energy-yielding metabolism. The following wording reflects the scientific evidence: “glucose contributes to energy-yielding metabolism”. In order to bear the claim, a food should be a significant source of glucose. Reference intake values for glycaemic carbohydrates have been established for labelling purposes in Regulation (EU) No. 1169/2011. The target population is the general population. © European Food Safety Authority, 2012

KEY WORDS

Glucose, energy-yielding metabolism, health claims

¹ On request from the Competent Authority of Germany following an application by Dextro Energy GmbH & Co. KG, Question No EFSA-Q-2012-00266, adopted on 25 April 2012.

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SUMMARY

Following an application from Dextro Energy GmbH & Co. KG, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Germany, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to glucose and “it is metabolised within body’s normal energy metabolism”.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.

The food constituent that is the subject of the health claim is glucose. Glucose can be consumed in the diet as a monosaccharide or be obtained from disaccharides, oligosaccharides and polysaccharides, which are digested and absorbed in the human small intestine and provide glucose to body cells as a source of energy. Besides glucose itself, the main glycaemic carbohydrates providing glucose in the diet are sucrose and lactose (disaccharides), as well as malto-oligosaccharides and starch (polysaccharides). This evaluation refers to glucose from all dietary sources. The Panel considers that the food constituent, glucose, which is the subject of the health claim, is sufficiently characterised.

The claimed effect is “it is metabolised within body’s normal energy metabolism”. The target population proposed by the applicant is the general population. In the context of the information and clarifications provided by the applicant during the validation of this application, the Panel notes that the claimed effect refers to the contribution of the food constituent to energy-yielding metabolism. The Panel considers that contribution to energy-yielding metabolism is a beneficial physiological effect.

It is well established that glucose is used within cells as a source of energy. The oxidation of glucose leading to CO₂ and water releases energy in the form of adenosine triphosphate, which is required by the body for all metabolic processes, as well as for the performance of any function or activity. Glucose contributes to energy-yielding metabolism as a source of energy, which is a property inherent to the food constituent.

The Panel notes that the publications provided by the applicant as being pertinent to the claim do not add new information to the well established role of glucose in energy-yielding metabolism as a source of energy.

The Panel concludes that a cause and effect relationship has been established between the intake of glucose and contribution to energy-yielding metabolism.

The Panel considers that the following wording reflects the scientific evidence: “glucose contributes to energy-yielding metabolism”.

In order to bear the claim, a food should be a significant source of glucose. Reference intake values for glycaemic carbohydrates have been established for labelling purposes in Regulation (EU) No. 1169/2011. The target population is the general population.

TABLE OF CONTENTS

Abstract	1
Summary	2
Table of contents	3
Background	4
Terms of reference	4
EFSA Disclaimer.....	4
Information provided by the applicant	5
Assessment	7
1. Characterisation of the food/constituent	7
2. Relevance of the claimed effect to human health.....	7
3. Scientific substantiation of the claimed effect	7
4. Panel's comments on the proposed wording.....	8
5. Conditions and restrictions of use	8
Conclusions	8
Documentation provided to EFSA	9
References	9
Glossary/Abbreviations.....	10

BACKGROUND

Regulation (EC) No 1924/2006⁴ harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health) which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Art 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA

- The application was received on 27/01/2012.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- On 12/03/2012, during the validation process of the application, EFSA sent a request to the applicant to provide clarifications/missing information.
- The applicant provided the clarifications/missing information on 29/03/2012.
- The scientific evaluation procedure started on 30/03/2012.
- During its meeting on 25/04/2012, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to glucose and contribution to energy-yielding metabolism.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: glucose and "it is metabolised within body's normal energy metabolism".

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of glucose, a positive assessment of its safety, nor a decision on whether glucose is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Dextro Energy GmbH & Co. KG, Hafenstrasse 77, 47809, Krefeld, Germany.

Food/constituent as stated by the applicant

According to the applicant, glucose (synonymous dextrose), $C_6H_{12}O_6$, $M=180.16$ g/mol

Health relationship as claimed by the applicant

According to the applicant, "glucose is the preferred energy source for most body cells including the brain which requires glucose for its energy needs. Glucose is ingested in form of monosaccharides or in form of polysaccharides, mainly starch, which has to be broken down into its constituent monosaccharide glucose before absorption. Glucose is stored in the liver and muscles as the branched polymer glycogen. Although it occurs in concentrations of up to 6 % of liver mass but only 1 % of muscle, muscle mass is so much greater that it represents three to four times as much glycogen as stored in the liver. Muscle glycogen is mainly used by the muscle, but liver glycogen is for storage, hydrolysis and export as glucose, and the maintenance blood glucose. Endogenous energy sources include blood glucose, muscle and liver glycogen. The recommended dietary allowance for carbohydrates is set at 130 g/day for adults. This value is based on the amount of available carbohydrate that can provide an adequate supply of glucose for the brain and the central nervous system cells without the need for additional glucose and its production from ingested proteins or triacylglycerols. Body's energy requirement rises with increasing physical activity.

The claimed effect was thoroughly examined in scientific analyses and studies and is now well established in books specialized in natural science. It is generally accepted that one metabolic pathway for glucose is its metabolism within the energy-yielding metabolism via glycolysis, citrate cycle and oxidative phosphorylation which leads to the formation of adenosine triphosphate (ATP), water and carbon dioxide. Thus the claimed effect refers to a general function of glucose within the human body, agreeing that the EFSA panel on Dietetic Products, Nutrition and Allergies has considered previously the contribution of glucose to body's normal energy-yielding metabolism as a beneficial physiological effect in general. Furthermore, the relationship between glucose and the claimed effect contribution to body's normal energy-yielding metabolism can also be substantiated by recent studies which have shown significant relationships between glucose ingestion and oxidation of glucose during physical activity. The immediate source of energy to sustain cellular processes, including muscular contraction, comes from hydrolysis of ATP. ATP is stored in muscle cells which can give high-power output for a few seconds. If the maximum effort lasts for 30 seconds or longer, then breakdown of muscle glycogen and subsequent degradation within glycolysis, citrate cycle and respiratory chain can supply the energy by producing ATP. Most physical activity requires an energy source that can power muscles for longer periods. The store of carbohydrates usually suffices for just 1 to 3 hours of physical exertion, depending on the intensity of effort, so additional glucose is needed during exercise. Ingestion of glucose increases glucose uptake when it is taken in during prolonged, strenuous exercise. In conclusion endogenous (muscle glycogen) and exogenous (additional glucose) glucose has to be oxidized to supply muscle with energy during physical activity. Therefore, total as well as endogenous and exogenous glucose respectively carbohydrate oxidation during physical activity is also used to assess the claimed effect.

Numerous studies have shown significant relationships between glucose ingestion and the oxidation of glucose respectively carbohydrates (total, endogenous and exogenous oxidation). This underlines that glucose is metabolized within body's normal energy metabolism and shows as well that this is beneficial for human health. For example one study showed significantly higher rates of total carbohydrate oxidation rates during exercise after glucose and maltodextrin ingestion (0.7 g/kg body

mass) compared to placebo (2.35 \pm 0.37 vs. 1.97 \pm 0.33 g/min; $p<0.001$). During physical performance the carbohydrate oxidation rates were significantly higher ($p<0.05$) by ingestion of similar quantities of glucose (1 g/kg body mass) compared to placebo (2.34 \pm 0.09 vs. 2.11 \pm 0.09 g/min). Furthermore, earlier studies have shown that glucose ingestion (200 g) during exercise results in augmented uptake and oxidation of glucose by the exercising muscle compared to placebo. Finally, glucose feedings (120 g) upon exercise leads to 0.53 g/min greater rate of carbohydrate utilization than during placebo trial. It should be noted that factors such as the carbohydrate content of the habitual diet or intake during training sessions may play a role in determine capacity of oxidizing carbohydrates. Nevertheless, the principal contribution of glucose to normal energy-yielding metabolism is unaffected. Muscle glycogen use increases after 90 min exercise after consumption of glucose solution (6.4 % glucose in 8 ml solution/kg body mass) compared to placebo (4.2 \pm 2.8 mmol/kg dry mass*min vs. 2.5 \pm 0.7 mmol/kg dry mass*min; $p=0.1$)”.

Description of the mechanism(s) by which the food/constituent exerts the claimed effect as proposed by the applicant

According to the applicant, “the claimed effect was thoroughly examined in scientific analysis and studies and is well established in scientific literature. Furthermore, the mechanism by which glucose exerts the claimed effect is described below.

Glucose is the preferred energy source for most body cells including the brain which requires glucose for its energy needs. Thus glucose is metabolized within body’s normal energy metabolism; this is beneficial for human health. Glucose is ingested in form of monosaccharides or in form of polysaccharides like starch, which has to be broken down into its constituent monosaccharides (glucose) before they can be absorbed and metabolized.

Depending on body’s energy requirement glucose is used to generate adenosine triphosphate (ATP) via glycolysis, citrate cycle and oxidative phosphorylation. Glucose is stored in the liver and muscle as the branched polymer glycogen. Although it occurs in concentrations of up to 6 % of liver mass but only 1 % of muscle, muscle mass is so much greater that it represents three to four times as much glycogen as stored in the liver. Muscle glycogen is mainly used by the muscle, but liver glycogen is for storage, hydrolysis with subsequent export as glucose, and the maintenance of blood glucose concentration. The immediate source of energy to sustain cellular processes, including muscular contraction comes from hydrolysis of ATP. Thus it is a beneficial physiological effect because glucose is needed to yield energy in form of ATP to sustain cellular processes, including muscular contraction”.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “glucose is metabolized within body’s normal energy metabolism”.

Specific conditions of use as proposed by the applicant

As proposed by the applicant, “the target population for consumption of glucose which is metabolized in the normal energy metabolism is the normal population as the contribution of glucose to the normal energy-yielding metabolism is a general biochemical principle occurring in all individuals”.

According to the applicant, “the quantity of glucose required to obtain the claimed effect is 130 g/day for adults during resting state. This value is based on the amount of available carbohydrate that can provide an adequate supply of glucose for brain and central nervous system cells without the need for additional glucose. In addition to the glucose requirement to ensure the normal energy-yielding metabolism, glucose requirement rises with increasing physical activity. The quantity of glucose required during physical performance is less than 30 g/h (0.5 g/min) for sports lasting 1 h, 30-60 g/h

(0.5-1.0 g/min) for sports of longer duration and 90 g/h (1.5 g/min) for events >2.5 h. 50-75 g ingestion as a single bolus is effective as well. Prolonging the rate of glucose absorption enhances insulin economy and glucose disposal. A recent study showed that a mild rebound hypoglycaemia following preexercise glucose ingestion does not affect performance. Altering the timing of the ingestion (15, 45 or 75 min before exercise) results in differences in plasma glucose/insulin responses which disappeared within 10 min of exercise and which had no effect on performance. Ingestion of carbohydrates in the form of a solid bar results in similar mean and peak exogenous carbohydrate oxidation rates and showed similar oxidation efficiency as an isocarbohydrated drink. It should be noted that factors such as the carbohydrate content of the habitual diet or intake during training sessions may play a role in determine capacity of oxidizing carbohydrates ingested. Nevertheless, the principal contribution of glucose to body's normal energy-yielding metabolism is unaffected".

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is glucose.

Glucose can be consumed in the diet as a monosaccharide or be obtained from disaccharides, oligosaccharides and polysaccharides, which are digested and absorbed in the human small intestine and provide glucose to body cells as a source of energy. Besides glucose itself, the main glycaemic carbohydrates providing glucose in the diet are sucrose and lactose (disaccharides), as well as malto-oligosaccharides and starch (polysaccharides) (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010; FAO/WHO, 1998).

This evaluation refers to glucose from all dietary sources.

The Panel considers that the food constituent, glucose, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect is "it is metabolised within body's normal energy metabolism". The target population proposed by the applicant is the general population.

In the context of the information provided, and in the context of the clarifications provided by the applicant during the validation of this application, the Panel notes that the claimed effect refers to the contribution of the food constituent to energy-yielding metabolism.

The Panel considers that contribution to energy-yielding metabolism is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed without any selection limits using different combinations of the search terms glucose, energy metabolism, carbohydrate oxidation, endogenous carbohydrate oxidation, exogenous carbohydrate oxidation, carbohydrate utilisation and exercise in order to identify publications on "the relationship between glucose and energy metabolism as well as oxidation or utilisation of glucose or carbohydrates during physical activity in human or animal studies". The Panel notes that the search is poorly described in the application (e.g. search dates and details regarding inclusion and exclusion criteria are not provided) and unsuitable for identifying all publications related to glucose intakes from all sources, particularly from di- and polysaccharides. From the 49 publications identified, 18 were excluded as not being pertinent to the claim.

The 31 publications considered by the applicant as being pertinent to the claim include data from 29 human intervention studies on the effects of different types of glycaemic carbohydrates administered primarily in liquid form (e.g. glucose and maltodextrin given either alone, together, or in combination with sucrose and/or fructose) before and/or during different types of physical exercise on carbohydrate/glucose oxidation rates compared to placebo (mostly water) in different subgroups of the adult population. A narrative review on consumption of carbohydrates during low, moderate or high intensity physical exercise was also identified as being pertinent to the claim. One animal study in horses using an administration route irrelevant to human nutrition (intravenous) was provided as supporting evidence.

It is well established that glucose is used within cells as a source of energy. The oxidation of glucose leading to CO₂ and water releases energy in the form of ATP, which is required by the body for all metabolic processes, as well as for the performance of any function or activity. Glucose contributes to energy-yielding metabolism as a source of energy, which is a property inherent to the food constituent.

The Panel notes that the publications provided by the applicant as being pertinent to the claim do not add new information on the well established role of glucose in energy-yielding metabolism as a source of energy.

The Panel concludes that a cause and effect relationship has been established between the intake of glucose and contribution to energy-yielding metabolism.

4. Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: "glucose contributes to energy-yielding metabolism".

5. Conditions and restrictions of use

In order to bear the claim, a food should be a significant source of glucose. Reference intake values for glycaemic carbohydrates have been established for labelling purposes in Regulation (EU) No. 1169/2011⁵. The target population is the general population.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, glucose, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect is "it is metabolised within body's normal energy metabolism". The proposed target population is the general population. Contribution to energy-yielding metabolism is a beneficial physiological effect.
- A cause and effect relationship has been established between the intake of glucose and contribution to energy-yielding metabolism.

⁵ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. OJ L 304, 22.11.2011, p. 18–63.

- The following wording reflects the scientific evidence: “glucose contributes to energy-yielding metabolism”.
- In order to bear the claim, a food should be a significant source of glucose. Reference intake values for glycaemic carbohydrates have been established for labelling purposes in Regulation (EU) No. 1169/2011. The target population is the general population.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on glucose and contribution to energy-yielding metabolism pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0322_DE). March 2012. Submitted by Dextro Energy GmbH & Co. KG.

REFERENCES

EFSA Panel on Dietetic Products, Nutrition, and Allergies (NDA), 2010. Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre. EFSA Journal 8(3):1462, 77 pp.

FAO/WHO (Food and Agriculture Organization/World Health Organization), 1998. Carbohydrates in human nutrition. Report of a Joint FAO/WHO expert consultation. FAO Food and Nutrition Paper - 66, Rome.

GLOSSARY/ABBREVIATIONS

ATP Adenosine Triphosphate